

**McNEIL****RECEIVED**NEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034
FEB 25 1999Page _____ of _____
BY _____

FEB 25 1999 by FDA on 11/15/93	
UFF/Out report #	
FDA use only	

A. Patient information

1. Patient identifier	2. Age at time of event: 72 yrs or Date of birth: _____	3. Sex (X) female () male	4. Weight 161 lbs or kgs
In confidence			

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 TYLENOL Analgesic Unknown	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 2 tablets, q4h, po	#1 unknown-3/6/96; 3-4 days
#2	#2
4. Diagnosis for use (indication)	
#1 leg pain, arthritic pain, temperatures	
#2	
5. Event abated after use stopped or dose reduced	
#1 () Yes () No (X) N/A	
#2 () Yes () No () N/A	
6. Lot # (if known)	7. Exp. date (if known)
#1 Unknown	#1 Unknown
#2	#2
8. Event reappeared after reintroduction	
#1 () Yes () No (X) N/A	
#2 () Yes () No () N/A	
9. NDC # - for product problems only (if known)	
#1	
#2	
10. Concomitant medical products and therapy dates (exclude treatment of event) PERCOCET®, digoxin, BUMEX®, insulin, VASOTEC®, lisinopril, PERCODAN®, allopurinol, ULTRAM®, AMBIEN®, ZAROXOLYN®, phenobarbital, ASA, mini-nebs, VANCERIL®, unspecified abx & cough medicines a few days PTA, prednisone, XANAX®, metaxalone	

E. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
() death (mo/day/yr)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
() other:	
3. Date of event 3/6/96 (mo/day/yr)	4. Date of this report 02/18/99 (mo/day/yr)

5. Describe event or problem

Notification via attorney letter of LIVER FAILURE & UREMIA (chronic renal failure w/hemodialysis) in a 72 yo F. Addl info rec'd 2/12/99: D/C sum indicates pt w/hx of insulin dependent diabetes was tx for URI approx 5d PTA. In spite of tx pt got progressively worse. Pt cont administering insulin despite not eating well. Pt's blood sugar decreased. Pt given glucose w/some response. In ER, pt w/T=103.8, RR=44, P=133. During hosp course, LFT's abnormal. GI consult (3/9/96) indicates took 2 tabs TYLENOL q4h for 3-4d w/last dose on 3/6/96. Recs indicate various drug hx's: TYLENOL & PERCOCET or TYLENOL & PERCODAN. According to d/c sum: IgG to hepatitis A & elevated Epstein-Barr viral titer. GI eval: "points to a toxic hepatitis which could be related to TYLENOL intake". Pt became azotemic (NPN INCREASED), renal function decreased & pt rec'd hemodialysis. Principal dx included: COPD w/acute exacerbation, CHF, acute HEPATITIS (most likely toxic in nature), Epstein-Barr viral infection, ACUTE (renal) KIDNEY FAILURE, hepatic encephalopathy (ACUTE BRAIN SYNDROME). D/c on 3/26/96.

6. Relevant tests/laboratory data, including dates

3/6/96: LDH=1003, SGOT=937, ALK Phos=139, SGPT=663, GGTP=193, TBili=0.9, PT=14.8, PTT=39.8, BUN=76, Cr=2, CPK=991 w/trace of 0.1, total LDH=1083; 3/7/96: liver & spleen scan: hepatomegaly & evidence of hepatocellular disease; 3/9/96 (See sec 87)

DSS

MAR 01 1999

ADVERSE EVENT REPORTING SYSTEM

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) arthritis, LVD, DJD, CHF, renal insufficiency, ischemic cardiomyopathy, s/p CABG, hx seizure, COPD, IDDM, doesn't drink ETOH; MKDA; Sec B6 cont: serum NH3=52, CMV IG greater than 2.50, CXR- cardiomegaly w/o failure, APAP level-undetectable; 3/11/96: TV 1:320; 3/12/96: alpha 1 antitrypsin=278; 3/15/96: ANA- tern speckled 1:320; HAAB; total=reactive; SSA=3.74, SSB=4.80

G. All manufacturers

1. Contact office name/address (& mfr site for devices)		2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Rd Ft. Washington, PA 19034		215-273-7820
3. Report source (check all that apply)		
() foreign		
() study		
() literature		
() consumer		
() health professional		
() user facility		
() company representative		
() distributor		
(X) other: attorney		
4. Date received by manufacturer (mo/day/yr) 02/12/99	5. (A) NDA # 17-552	
6. If IND, protocol #	IND #	
	PLA #	
	pre-1938 () Yes	
7. Type of report (check all that apply)	OTC product (X) Yes	
() 5-day (X) 15-day		
() 10-day () periodic		
() Initial (X) follow-up # 1		
8. Adverse event term(s)		
LIVER FAILURE	UREMIA	
NPN INCREASED	HEPATITIS	
KIDNEY FAIL ACU	BRAIN SYND ACUT	
9. Mfr. report number		
0700202A		

E. Initial reporter

1. Name, address & phone #		
[Redacted]		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
() Yes (X) No	attorney	() Yes () No (X) Unk



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.